## **REMARKS**

Claims 1-16 are currently pending in this application.

Applicants have amended claims.

Applicants have amended claim 1 to more specifically describe the claimed preparations Specifically, the preparations are able to be administered systemically.

Applicants have amended claims 5 and 6 to direct the claims to elected subject matter.

None of the amendments presented herein constitute new matter. Applicant addresses below the outstanding rejections.

## THE OBJECTIONS

The Examiner has objected to claims 5 and 6 contending that they encompass non-elected subject matter. Applicants have amended the claims to obviate this objection. Claims 10-16 stand rejected as reciting improper dependencies. Applicants have amended claims 10 and 14 to correct the dependencies of claims 10-16.

#### **SPECIFICATION**

The Examiner has objected to the disclosure because the Specification refers to Figures 1, 2 and 3 but no Figures are with the file. Applicants enclose a set of Figures as they appeared in the in the application to which the pending application claims priority. Accordingly, their submission is not new matter. Further, applicants enclose a copy of a return postcard dated June 20, 2001 indicating that the complete International Application and Translation were received by the USPTO.

## THE REJECTIONS

35 U.S.C. § 102

Claims 1-7 and 10-16 stand rejected under 35 U.S.C. § 102(a) and (e) as being "anticipated by" <u>Greenwood '735</u>. Specifically, the Examiner contends that <u>Greenwood '735</u> teaches an injectable, stable, immortalized, non-tumorigenic rat retinal cell line comprising the additional noted features. Applicants traverse the rejection based on the amendments and arguments presented herein.

As described in the Specification (in reference to the application from which <u>Greenwood '735</u> claims priority), the prior art did not envisage the deleterious effect induced by the presence of cell aggregates in administered formulations (page 4, lines 1-5). Accordingly, the instant invention is directed to compositions free of deleterious aggregates which may be safely administered to a patient in need of such treatment. There is no suggestion in the Examiner's arguments that <u>Greenwood '735</u> provided the requisite teaching of this improvement. The Examiner has not provided any evidence that the cell preparations of <u>Greenwood '735</u> were formulated into a preparation capable of being administered to a patient. Applicants respectfully request that the Examiner withdraw this rejection.

Claims 1-7 and 10-16 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Greenwood '139. The Examiner has cited this document as having an identical disclosure to Greenwood '735 and recites the identical reasons for its applicability. Accordingly, the applicants respectfully request that the Examiner withdraw this rejection for the same reasons as described above.

# 35 U.S.C. § 103

Claim 9 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Greenwood '735, Greenwood '624 as applied to claims 1, 3-6, 10-11 and 13-16 above and further in view of Roux. Specifically, the Examiner contends that the cited references teach an injectable, stable, immortalized, non-tumorigenic rat retinal pigmenty cell line comprising a heat sensitive SV40 T antigen. The Examiner contends that Roux teaches a method of making cell suspensions of adherent microvascular enothelial cells. Applicants traverse.

The instant claims as amended are directed to specific cellular preparations that are capable of being administered systemically. The cell suspensions noted by the Examiner were not formulated for systemic administration. In fact, there is no suggestion or motivation to formulate unaggregated cell suspensions for systemic administration. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw the rejection.

# 35 U.S.C. § 112, first paragraph

Claims 10-16 stand rejected under 35 U.S.C. § 112, first paragraph as failing to comply with the enablement requirement. Specifically, the Examiner contends that claims 10-16 are directed towards a method of gene therapy. Applicants traverse.

Applicants' claimed invention is a cell preparation. Although the cells may be transfected with a gene, administration of the cell preparation does not result in the delivery of that gene to the subject's chromosome(s). Accordingly, the state of the art with respect to gene therapy has no impact on the enablement of the instant invention. Applicants respectfully request that the Examiner reconsider and withdraw the rejection.

# 35 U.S.C. § 112, second paragraph

Claim 1 stands rejected under 35 U.S.C. § 112, second paragraph. Specifically, the Examiner contends that the term "said patent" lacks antecedent basis. Applicants have amended claim 1 to recite "subject" instead of "patent" thus obviating the rejection.

Claim 8 stands rejected as because the Examiner contends it is not clear what is meant by "a nucleic acid sequence expressing an agent preventing aggregate formation or inhibiting the expression of an agent preventing the formation of aggregates". Applicants have amended the claim to recite a nucleic acid sequence expressing an agent that has the capacity to prevent aggregate formation or inhibit the expression of an agent. Applicants respectfully request that the Exainer withdraw the rejections under 35 U.S.C. § 112, second paragraph.

## **CONCLUSION**

Applicants request consideration and allowance of the pending claims.

Respectfully submitted,

Dated: **Keb. 1**, 2004

Ivor R. Elrifi, Reg. No. 39,529

Scott D. Miller, Reg. No. 43,803

Attorneys for Applicants

c/o MINTZ, LEVIN, COHN, FERRIS GLOVSKY AND POPEO P.C.

Chrysler Center 666 Third Avenue, 24<sup>th</sup> Floor

New York, New York 10017 Tel: (212) 935-3000

Fax: (212) 983-3115



Title: Marracellar (ell frapetations Optimally Transficted.	Applicant(s): 11005,1 Secope.  The following, DUE 6/2/01 at Box PCT, Assistant Commissioner for Patents, was received in the Mail Room on the date stamped hereon.	Certificate of Mailing by Express Mail   Cartificate of Mailing by Express Mail   Report   1.10   Label No. Et 73527622399   Report   Report   Cartificate   Cartificate	Antemational Application as Filed  Aranslation of International Application into  English  International Search Report  Second or Subsequent Preliminary	under PCT to the Claims	Oath or Declaration of the Inventor(s)    Control   Cont	Mailing Date Olyce 20/200
---	--	--	--	-------------------------	--	---------------------------

RECEIVED
FEB 1 2 2004
FECH CENTER 1600/2900

RECEIVED

MAY 2 5 2004

TECH CENTER 1600/2900